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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,882	09/15/2006	Siegfried Ansorge	P29677	4700

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/575,882	ANSORGE ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *97-116* is/are pending in the application.

4a) Of the above claim(s) *101,102 and 105-116* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *97-100,103 and 104* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/05/2009;11/30/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 101, 102, 105-116 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 6, 2009.

2. Applicant's election with traverse of invention group III, drawn to a composition and method of using the same for treating chronic neuronal diseases, such as Alzheimer's disease, Parkinson's disease, and compound A1.002 as the elected compound species in the reply filed on July 6, 2009 is acknowledged. The traversal is on the ground(s) that acute neuronal disease should be joined with chronic neuronal disease as there would be no burden to search both inventions. This is not found persuasive because chronic neuronal diseases and acute neuronal diseases as defined herein are drawn to distinct and unrelated diseases. Chronic neuronal diseases herein include Alzheimer's disease, Parkinson's disease, and Huntington disease. Acute neuronal diseases herein include ischemia-caused cerebral damage from stroke, cranio-cerebral trauma, cardiac arrest, myocardial infarction or heart surgery. Those diseases are distinct in their etiology, and symptoms. Treatment of one disease would have not been obvious for the other,

The requirement is still deemed proper and is therefore made FINAL.

3. Additional restriction group.

XI. Claims 107 and 110, drawn to a stent, classified in class 623, subclass 1.15.

Invention group XI and invention groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

group XI drawn to a stent, a distinct subject matter from invention groups I-X drawn to therapeutical method.

4. Claims 107 and 110 are withdrawn as drawn to non-elected invention.

5. Claims have been examined insofar as they read on elected inventions and species.

Claim Objections

6. Claim 98 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 98 recites compounds A1.007 and A1.011, which do not within the scope of claims 97.

Disclosure Objections

7. The disclosure is objected to because of the following informalities: the disclosure lacks a brief description of drawings.

Appropriate correction is required.

Claim Rejections 35 U.S.C. 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 103 and 104 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating chronic neuronal diseases, does not reasonably provide enablement for preventing those diseases. The specification does not enable any person

skilled in the art to which it pertains, or with which it is most nearly connected, to make and /or use the invention commensurate in scope with these claims.

10. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to In re Wands, 8 USPQ 2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factor to consider when assessing if a disclosure would have required undue experimentation. The court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art,

7) the predictability of the art, and

8) the breadth of the claims.

The claim recites the prevention of chronic neuronal diseases, particularly, Alzheimer's disease, Parkinson's disease. Alzheimer's disease is a chronic neuro-degenerative disease. The exact etiology is largely unknown. While there are progress in diagnosis of the disease and suppressing the development of the disease. There is no known method for curing the diseases, nor method for preventing the disease from happening. See, e.g., Ritzline et al. The application discloses that the compounds herein are alanyl aminopeptidase inhibitor useful for treating neuronal diseases. However, the application provides no working examples, guidance or direction for

preventing such diseases. It is noted that the pharmaceutical art generally is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The court in In re Fisher, 427 F.2d 833, 839; 166 USPQ 18, 24 (CCPA 1970) held that, "in case involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved." The more unpredictable an area, the more specific enablement is need in order to satisfy the statue. The Unpredictability is more apparent where the diseases disclosed in the specification are as complex and diverse in etiology and patient populations as the many types and causes Alzheimer's diseases. See, Sitzline et al. Thus it would require undue experimentation for the skilled artisan to practice the invention as broadly claimed.

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 103 and 104 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is

(a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 13 and 14 recites the broad recitation chronic neuronal diseases, and the claim also recites "in particular Morbus Alzheimer …" which is the narrower statement of the range/limitation.

4. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors. For example, "Morbus Alzheimer", "Morbus Parkinson" etc. are not commonly used in English.

Claim Rejections 35 U.S.C. 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 97-100 and 103-104 are rejected under 35 U.S.C. 102(a or e) as being anticipated by Steffan et al. (WO 02/090534).

1. Steffan et al. teach a method of treating Alzheimer's disease comprising administering to the patient a histone deacetylase inhibitor. See, particularly, claim 37. Scriptaid (recited here as A1.009 in claim 98) is disclosed as one of the histone deacetylase inhibitors. See, particularly,

pages 25-28. The histone deacetylase inhibitors are formulated with one or more adjuvant and/or pharmaceutical acceptable carrier. See, particularly page 32. As to the recited in the claims. i.e., inhibiting ananyl aminopeptidase, note, the instant claims are directed to affecting a biochemical pathway with an old and well known compounds. The argument that such claims are not directed to the old and well known ultimate utility (treating Alzheimer's disease) for the compounds, e.g., scriptaid, are not probative. It is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds is old and well known rendering the claimed subject matter anticipated.

Claim Rejections 35 U.S.C. 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 97 and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eckstein et al. in view of Nakanishi et al. and Emerson et al. (US 5,639,794).

9. Eckstein et al. teaches that hydroxamic acid derivatives Ar-Y-CONHOH, wherein Ar is phenyl substituted with alkyl and/or halogen, and Y is CH2, ArCH, O(CH2)n, SCH2 or NHCH, are systemic fungicides. 2-Methyl-4-chlorophenoxyacetylhydroxamic acid is particularly disclosed. See, particularly, the abstract and table 1 at page 991.

10. Eckstein et al. do not teach expressly the 2-Methyl-4-chlorophenoxy propionohydroxamic acid, nor a composition comprising the hydroxamic acid derivative, a pharmaceutical acceptable carrier and a pharmaceutical acceptable adjuvant.

11. However, Nakanishi et al. teaches that Tween type surfactants are pharmaceutical acceptable adjuvants. See, particularly, page 3258. Emerson et al. teaches that Tween type surfactant is commonly used in agrichemical product, such as antifungal composition, particularly, for those applied to vegetable, fruit, because of little concerns of toxicity. See, particularly, columns 8-10 and the claims.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a hydroxamic acid derivative Ar-Y-CONHOH with Ar as 2-methyl-4-chlorophenyl and Y is O(CH2)2, and a composition comprising the same with water and Tween type surfactant, particularly for applying to fruit or vegetable.

A person of ordinary skill in the art would have been motivated to make a hydroxamic acid derivative Ar-Y-CONHOH with Ar as 2-methyl-4-chlorophenyl and Y is O(CH2)2, and a composition comprising the same with water and Tween type surfactant, particularly for applying to fruit or vegetable because such compounds are generally known to be useful as antifungal agents. Further, the compound disclosed by Eckstein et al. that are structural

homologs of the instantly claimed compounds, i.e., they differ only by a CH_2 group. One having ordinary skill in the art would have been motivated to prepare the instantly claimed compound because such structurally homologous compounds are expected to possess similar properties. It has been held that compounds that are structurally homologous to prior art compounds are prima facie obvious, absent a showing of unexpected results. In re Hass, 60 USPQ 544 (CCPA 1944); In re Henze, 85 USPQ 261 (CCPA 1950). The employment of water and Tween type surfactant with the hydroxamic acid derivative for making an antifungal composition would have been obvious because such carrier and adjuvant are taught to be useful as non-toxical carrier particularly for application for eatable plants.

Remarks

The method of using the elected species for treating of chronic neuronal disease is found allowable as the prior art as a whole do no teach or fairly suggest such utility for the compound. The search has expanded a non-elected species.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shengjun Wang/
Primary Examiner, Art Unit 1617